

REMARKS

Claims 15, 18-21, 23-26, and 33-59 are all the claims pending in the application.

Applicants have rewritten independent Claim 15 as a product-by-process claim directed to an equol-containing composition. The composition of Claim 15 is obtained by incubating at least one strain selected from the group consisting of *Bacteroides* E-23-15, which has been deposited as FERM BP-6435, *Streptococcus* E-23-17, which has been deposited as FERM BP-6436, and *Streptococcus* A6G-225, which has been deposited as FERM BP-6437, with a daidzein-containing substance.

Claim 51 has been amended to render it consistent with amended Claim 15.

No new matter is added.

I. REQUEST FOR REJOINDER OF CLAIMS 33-59

As stated at page 3 of the Office Action mailed August 23, 2006, process claims that depend from, or otherwise include all of the recitations of patentable product claims, will be rejoined as a matter of right.

Thus, Applicants request rejoinder of method Claims 33-50, as they directly or indirectly depend from Claim 15.

In addition, Applicants request rejoinder of method Claims 51-59, which directly or indirectly depend from Claim 15.

II. RESPONSE TO REJECTION UNDER 35 U.S.C. § 103

Referring to pages 6 and 7 of the Office Action, Claims 15, 18-21, and 23-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 9-238647 ("Ishikawa") taken with YU-CHEN CHANG ET AL., Metabolism of Daidzein and Genistein by Intestinal Bacteria ("Chang") and U.S. Patent No. 5,902,578 ("Halpin-Dohnalek").

Applicants respectfully traverse.

Ishikawa is not valid prior art against the claims of the present application. Ishikawa was published on September 16, 1997, *i.e.*, after Applicants' priority date of August 5, 1997.

Therefore, the present §103 rejection should be withdrawn in view of the submission herewith of a sworn translation into English of Applicants' priority document. Applicants confirm that the subject matter of the presently rejected claims is supported by the disclosure of the priority document.

A similar rejection over Ishikawa was overcome in parent application no. 09/485,320 by the submission of the same sworn translation into English of Applicants' priority document.

Withdrawal of the present §103 rejection is requested.

III. RESPONSE TO REJECTIONS UNDER 35 U.S.C. § 102

Referring to pages 2-6 of the Office Action, the examiner sets forth the following three §102 anticipation rejections:

Claims 15, 18, and 20-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Chang;

Claims 15, 20-21, and 23-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hutchins et al. (J. of American Dietetic Assoc., 1996, vol. 95, No. 5, pages 545-551) or Axelson et al. (Axelson, M.D. N. Kirk, R.D. Farrant, G. Cooley, A.M. Lawson, and K. D.R. Farrant, G. Cooley, A.M. Lawson, and K. D. R. Setchell. 1982. The identification of the weak oestrogen equol [7-hydroxy-3-(4'-hydroxyphenyl)chroman] in human urine. Biochemical Journal 201: 353-357) in light of Peschek-Bohmer et al. (<http://www.innerself.com/Health?urine.htm>. (from Urine Therapy: Nature's Elixir for Good Health 1997)); and

Claims 15 and 25-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tang et al. (1980. Effect of Equol on Oestrogen Receptors and on Synthesis of DNA and Protein in the Immature Rat Uterus. Journal of endocrinology 85: 291-297).

Applicants respectfully traverse each of the §102 anticipation rejections. The subject matter of the presently rejected claims is not disclosed by the presently applied art.

Claim 15 is the only independent claim. It is written in product-by-process format and is directed to an equol-containing composition. As recited in Claim 15, the composition is obtained by incubating at least one strain selected from the group consisting of *Bacteroides* E-23-15, which has been deposited as FERM BP-6435, *Streptococcus* E 23 17, which has been deposited as FERM BP-6436, and *Streptococcus* A6G-225, which has been deposited as FERM BP 6437, with a daidzein-containing substance. In other words, the presently claimed equol-containing composition is obtained by incubating a specific microorganism capable of metabolizing daidzein to equol with a daidzein-containing substance.

The structure or composition implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural or compositional characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).

In the present case, none of Chang, Hutchins, Axelson and Tang discloses incubating at least one strain selected from the group consisting of *Bacteroides* E-23-15, which has been deposited as FERM BP-6435, *Streptococcus* E 23 17, which has been deposited as FERM BP-6436, and *Streptococcus* A6G-225, which has been deposited as FERM BP 6437, with a daidzein-containing substance.

Chang merely discloses the fermentation of isoflavones and genistein with human fecal bacteria under anaerobic conditions to produce, *inter alia*, equol. Chang is silent about *Streptococcus intermedius* and *Streptococcus constellatus* being capable of metabolizing daidzein to equol.

Likewise, Hutchins and Tang do not teach or suggest which microorganisms have the ability to metabolize daidzein to equol among human fecal bacteria. In addition, Hutchins and Tang are silent about daidzein.

Applicants respectfully submit that if the combinations of microorganisms and starting materials are different, the contents of the fermented products are also different. What is more,

metabolites produced by microorganisms change according to the type of microorganisms, raw materials, incubating conditions, and so on.

Therefore, the presently claimed equol-containing composition neither is disclosed by or obvious from Chang, Hutchins, Axelson and Tang.

For the foregoing reasons, Applicants request reconsideration and withdrawal of the present §102 anticipation rejections.

IV. CONCLUSION

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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